FEB 1 1 2005

K 043094

510(k) Summary Information *Premarket Notification, Section 510(k)*	*LDR Spine USA* **DATE PREPARED:** **JANUARY 18, 2005**

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. ***Establishment Name*** **&** ***Contact Person:***

Name: ***LDR Spine USA***
4030 West Braker Lane
Suite 360
Austin, TX. 78759

Mr. Brian Burkinshaw
Director, Innovation & Technology Solutions
Telephone: 512-344-3304
Fax: 512-344-3350

2. ***Device Name:***

Trade Name: ***Easyspine System***

Common Name(s): Posterior lumbar spine system

Classification Name(s): Pedicle Screw Spinal System

4. ***Equivalent Predicate Device:***

Orthopedic Alliance Spine System, K033826, Orthopedic Alliance, LLC.

5. ***Classification(s):***

§ 888.3070 – Pedicle Screw Spinal System (Class II Uses)
(a) ***Identification.*** Pedicle screw spinal systems are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.

(b) ***Classification.*** (1) Class II (special controls), when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). These pedicle screw spinal systems must comply with the following special controls:

(i) Compliance with material standards;

(ii) Compliance with mechanical testing standards;

(iii) Compliance with biocompatibility standards; and

(iv) Labeling that contains these two statements in addition to other appropriate labeling information:

"Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis

with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."

"Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient."

Device Class: Class II for the requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): MNI, MNH

5. *Device Description:*

The LDR Easyspine® System consists of various screws, rods and connectors and is intended to provide temporary stabilization following surgery to fuse the thoraco-lumbar spine.

This system includes side-loading polyaxial screws, which allow the surgeon to easily insert the spinal rod using a posterior-lateral loading technique into the fixation components.

The rod opening of the screw heads can be positioned medially or laterally. The polyaxial locking mechanism of the standard screws allows a 20 degree angulation in all directions.

The dual-polyaxial α-screw (alpha screw) provides an additional 5 degrees of angulation to facilitate loading of the rod, even when the difference in pedicular screw angulation is significant relative to the next screw.

Crosslinks (transverse connectors) are provided to increase rotational stiffness of a given construct as desired by the clinician.

Rods consist of a single diameter (6.0mm) yet offer variable stiffness. Multiple lengths of spinal rods are included with this system as is typical for essentially all competitive systems. The variable stiffness/rigidity of the various rod offerings is accomplished by fabricating the rods with a machined flat surface on the rod, from one end to the other, following the longitudinal axis of each rod. Thus, the cross section of the rods (as measured at the flattened area), provide comparable strength and stiffness to other rods available in approved systems.

Materials:

Titanium Alloy	ASTM F136-92	ISO 5832-3

Testing Summary: Fatigue and static testing is complete. Samples were tested according to accepted engineering and scientific principals. Test results demonstrate that the system can be expected to perform in a manner equivalent to the comparison device.

6. *Summary Comparison Table:*

Feature Comparison Table:

FEATURE	*Easyspine System*	*Orthopedic Alliance Spine System*	SE?
Indications for Use:	degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous fusion (pseudarthrosis)	degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous fusion (pseudarthrosis)	YES
Design:	Posterior – pedicle screw/rod spine system	Posterior – pedicle screw/rod spine system	YES
Sterile:	Implants supplied sterile Instruments supplied nonsterile	Both supplied nonsterile	YES
Rod Diameter:	6mm	4mm	NO/YES
Material:	Titanium Alloy	CP titanium & titanium alloy	YES
Screw Sizes:	6 & 7mm	5, 6 & 7mm	YES
Manufacturer:	LDR Spine USA	Orthopedic Alliance, LLC	YES
Product Code:	MNI, MNH	MNI	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Mr. Brian Burkinshaw
Director Technology Solutions
LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, Texas 78759

Re: K043094
Trade/Device Name: Easyspine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: January 31, 2005
Received: February 2, 2005

Dear Mr. Burkinshaw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K043094

Device Name(s): ***Easyspine System***

Indications For Use:

The LDR Easyspine System is a posterior, noncervical, pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: spondylolisthesis (grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use __X__ OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109) (Optional format 1-2-96)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043094